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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/825,585	04/16/2004	Shigetoshi Kadota	0804.001.0002	8180
43446	7590	10/31/2007	EXAMINER	
CASTELLANO PLLC			FLOOD, MICHELE C	
P.O. Box 1555			ART UNIT	
Great Falls, VA 22066			PAPER NUMBER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/825,585

Applicant(s)

KADOTA ET AL.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,7,8,30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,7,8 and 30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6/5/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on August 15, 2007 with the cancellation of Claims 21-26 and the addition of newly added Claims 30 and 31. Further acknowledgment is made of the receipt and entry of the Declaration under 37 CFR 1.132 filed by Chia-Chin Sheu filed on August 15, 2007.

Election/Restrictions

Applicant's election with traverse of Group I, Claims 1-3, 7, 8 and 30 in the reply filed on August 15, 2007 is acknowledged. Applicant argues that the search of Claims 1-3, Claims 7- 8 (currently amended), and Claim 30 (newly added) along with the invention of newly added Claim 31, Group II, would not pose an additional burden on the Examiner. However, this is not found persuasive because the invention of Group I is directed to a composition for treating osteoporosis comprising a dried powder of culture of *Cordyceps sinensis* as an effective ingredient wherein the dried powder comprises a water extract of an organic solvent product of culture of *Cordyceps sinensis*, whereas the invention of Group II is directed to a composition for treating osteoporosis comprising a water extract of cultured mycelium of *Cordyceps sinensis* as an effective ingredient. Despite the fact that the inventions of Group I and Group II may be classified under the same class and subclass, the inventions are separate and distinct, each one from the other. For instance, these compositions

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are capable of separate manufacture, use or sale, as claimed, and are patentable (novel and unobvious) over each other (though they may be unpatentable because of the prior art) subjects. Further a reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-3, 7, 8 and 30 are under examination.

Terminal Disclaimer

The allowed application/patent being disclaimed has been improperly identified since the number used to identify the application number being disclaimed is incorrect. The correct number is 11/533,665.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

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The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the instant case, Applicant should avoid the use of the phrase, "The present Invention provides a", which appears in line 1 of the abstract. Applicant may overcome the objection by deleting the aforementioned phrase, and adding A. Applicant is also required to delete the underscore which appears between "Sinensis" and "or" in line 4 of the abstract; and to replace the capital "S" appearing in "Sinensis" with a lower case s to place the sentence in proper grammatical order.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 7, 8 and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The metes and bounds of Claim 1 are rendered indefinite by the phrase, "a water extract of an organic solvent extract product of culture of *Cordyceps sinensis*", because it is unclear as to how the extracted matter can be both a water extract and an organic solvent extract. The lack of clarity renders the claim ambiguous.

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Claim 30 recites the limitation "the at least one organic solvent" in line 1. There is insufficient antecedent basis for this limitation in the claim. Applicant may overcome the rejection by deleting "at least one".

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also, rejected under U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 7 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Koh et al. (U).

Applicant claims a composition for treating osteoporosis comprising a dried powder of culture of *Cordyceps sinensis* as an effective ingredient, wherein said dried powder comprises a water extract of an organic solvent extract product of culture of *Cordyceps sinensis*. Applicant further claims the composition according to claim 1, wherein the composition treats osteoporosis by suppressing a decrease of spongy bone density; wherein the *Cordyceps sinensis* is mycelium of *Cordyceps sinensis*; and, wherein at least one organic solvent is selected from the group consisting of alcohol, ester, alkane and halogenated alkane. Applicant

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further claims the composition according to Claim 7, wherein the alcohol is methanol or ethanol.

Koh teaches a composition comprising a dried powder comprising a water extract of an ethylacetate/methanol fraction of a mycelium culture of *Cordyceps sinensis*, on page 407, second paragraph of Column 2 to page 408, first paragraph of Column 1. Koh further teaches that the reference extract increased the proliferation of bone marrow cells in mice that had been fed the fungal water extract, on page 409, Column 1, lines 5-19. Although Koh does not teach the referenced fungal extract as an agent for treating osteoporosis or as an agent for suppressing the decrease of spongy bone density, the claimed functional effects are considered inherent to the extract taught by Koh because the fungus, the part of the fungus and the solvent used in the making of the *Cordyceps sinensis* extract are one and the same as disclosed in the instantly claimed invention of Applicant. Thus, a water extract of an organic extract product of culture of *Cordyceps sinensis* for treating osteoporosis is inherent to the composition taught by Koh absent evidence to the contrary. Moreover, Koh expressly teaches that the reference extract increased the proliferation of bone marrow (spongy bone) cells both in an *in vitro* and *in vivo*.

The reference anticipates the claimed subject matter.

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Allowable Subject Matter

Claim 30 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is 571-272-0964. The examiner can normally be reached on 7:00 am - 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


MICHELE FLOOD
PRIMARY EXAMINER

Michele Flood
Primary Examiner
Art Unit 1655

MCF
October 27, 2007